

REMARKS

Claims 1, 3-11, 14-19, 21-32 and 34-36 are pending. Claims 25-30 have been withdrawn from consideration pursuant to a restriction requirement. Claims 2, 12, 13, 20 and 33 have been canceled. Thus, claims 1, 3-11, 14-19, 21-24, 31, 32 and 34-36 are pending and stand variously rejected under 35 U.S.C. §§ 112, 102 and 103.

By amendment herein, claim 1 has been reformatted and amended to incorporate the limitations of claim 18. Accordingly, claim 18 has been canceled, without prejudice or disclaimer. Claim 31 has been amended to indicate that at least one of the bioactive materials is attached to the coil, as described for example on page 5, lines 3-5. In addition, claims 32 and 35 have been amended to provide adequate antecedent basis in each claim. Finally, claims 34 and 35 have been amended to indicate that the vaso-occlusive member and/or particulate material are absorbable, as described, for example, on page 10, lines 24-25. These amendments are made solely to further prosecution and entry thereof is respectfully requested. Applicant reserves the right to file a continuation or divisional application directed to the subject matter of the original claims during the pendency of this application.

Applicant acknowledges with appreciation withdrawal of the rejection of claims 1-24 under 35 U.S.C. § 112, first paragraph as well as withdrawal of the rejection of claims 31, 32 and 34-36 under 35 U.S.C. § 112, second paragraph.

In view of the foregoing amendments and following remarks, Applicant respectfully requests reconsideration of the application and withdrawal of the remaining rejections.

Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 34 and 35 stand rejected under 35 U.S.C. 112, first paragraph as allegedly not described by the specification in such a way as to convey that the inventor was in possession of the claimed subject matter at the time of filing. (Final Office Action, paragraph 4). In particular, the term "biodegradable" is allegedly not described in the specification. (Office Action, paragraph 4).

For the reasons of record, Applicant submits that the term biodegradable is fully supported by the specification as filed. Nonetheless, to expedite prosecution, the term "biodegradable" has been replaced by the term "absorbable," as described for example on page 10, line 24-25 of the specification. In view of the foregoing, Applicant submits that the written description requirement has been fully satisfied and respectfully request withdrawal of the rejections.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 32 and 35 stand rejected under 35 U.S.C. 112, second paragraph as allegedly vague and indefinite. (Finally Office Action, paragraphs 6-8). In particular, there is alleged to be lack of antecedent basis for the recitation “particulate liquid embolic material” in claim 32 and the term “particulate material” in claim 35. Applicant has amended the claims to obviate any concerns about antecedent basis. Accordingly, withdrawal of these rejections is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 1, 3, 4, 5, 6, 11, 14, 16, 18, 19, 21, 22 and 24 and stand variously rejected as allegedly anticipated by a variety of references. (Final Office Action, paragraphs 11-14). Applicant addresses the rejections in turn.

Rejections Based on Eder

Claims 1, 3, 4, 11, 14, 18, 19, 21 and 24 remain rejected under § 102(b) as allegedly obvious over U.S. Patent No. 5,980,550 (hereinafter “Eder”). Eder is cited for disclosing a vaso-occlusive coil, a thrombus-stabilizing molecule and a bioactive material in the form of cytokine VEGF. (Office Action, paragraph 11). In response to arguments that that Eder necessarily includes more components than the claimed devices, the Office states:

Regarding the argument that Eder ‘550 includes three components and has more elements than the claimed invention, Eder’s water soluble coating includes the use of at least one cytokine (growth factors), which makes the outer coating of Eder part of the bioactive material as claimed (column 5, line 64-column 6, line 15). Therefore, the rejection over Eder is proper. (Final Office Action, paragraph 20).

Applicant again traverses the rejection and supporting remarks.

Eder fails to anticipate any of the currently pending claims. As previously noted, it is well settled that claims including fewer elements than contained in the reference are not anticipated by that reference. *See, e.g., Kalman v. Kimberly-Clark Corp.* 218 USPQ 781 (Fed. Cir. 1983), *cert. denied*, 484 US 1007 (1988). Here, the claims use the closed transition language “consisting of.” Therefore, the pending claims are necessarily limited to the elements listed in the claims and, as such, necessarily exclude a water-soluble coating, as required by Eder. The fact that Eder’s water-soluble coating may contain a cytokine is utterly irrelevant to the question at hand. What is relevant to determining patentability of the pending claims is the fact that Eder requires the presence of a water-soluble coating (with or without cytokines), while the claimed invention never includes such as coating. Accordingly, the claimed compositions

and methods always include fewer elements than contained in Eder and, accordingly, Eder cannot anticipate any of the pending claims.

Rejections Based on Callister, Ji '022, and Schwartz

Claims 1, 5, 6, 16, 19 and 22 are alleged to be anticipated under 102(a) by U.S. Patent No. 6,096,052 (hereinafter "Callister"). In addition, claims 1 and 16 stand rejected as allegedly anticipated by U.S. Patent No. 5,894,022 (hereinafter "Ji '022"). Finally, claims 1, 7, 8, 11, 17, 19 and 23 stand rejected as allegedly anticipated by U.S. Patent No. 5,800,507 (hereinafter "Schwartz").

Because none of the references describe or demonstrate the subject matter of pending claims 1, 5, 6, 16, 19 or 22, Applicant traverses.

The pending claims are directed to vaso-occlusive compositions consisting of a vaso-occlusive member and one or more additional bioactive materials. Furthermore, the claims now specify that the vaso-occlusive member is selected from the group of one or more vaso-occlusive coils, one or more filters, one or more retention devices and combinations thereof, as previously recited in claim 18. The Office has acknowledged that Callister, Ji'022, and Schwartz do not anticipate the vaso-occlusive compositions comprising the particular vaso-occlusive members as presently claimed. Accordingly, this rejection has been obviated and Applicant respectfully requests it be withdrawn.

Rejection Under 35 U.S.C. § 103

The Examiner has also maintained the rejection of claims 9 and 10 as allegedly obvious over Schwartz. (Final Office Action, paragraph 16). In addition, claim 15 remains rejected as allegedly obvious over Schwartz in view of U.S. Patent No. 5,891,192 (hereinafter "Murayama"). (Final Office Action, paragraph 17). Furthermore, claims 31, 32 and 34-36 are newly rejected as allegedly obvious over U.S. Patent No. 5,888,546 (hereinafter "Ji '546") in view of Ji '022. (Final Office Action, paragraph 18). Applicant addresses the rejections in turn.

With regard to the rejections based on Schwartz, Applicant submits, for the reasons detailed above, that this reference fails entirely to disclose a vaso-occlusive member that is a coil, a retention device and/or a filter, as presently claimed. For its part, Murayama also fails to teach vaso-occlusive members as claimed. Therefore, Schwartz, alone or in combination with Murayama, cannot render pending claims 9, 10 and 15 obvious.

Turning to the rejection of claims 31, 32 and 34-36 over Ji '546 in view of Ji '022, Applicant submits that this combination fails to teach or suggest compositions in which at least one of the bioactive materials is attached to the vaso-occlusive coil, as claimed. Rather, as admitted by the Office, Ji '022, the only reference to even mention coils, teaches that the coil is

used to hold an injected vaso-occlusive material in place. Thus, there is no disclosure in the combination of Ji '022 and Ji '0456 reference that renders the pending claims unpatentable.

In sum, there is no motivation within Schwartz or Murayama to arrive at the invention of claims 9, 10 and 15. Similarly, there is no motivation with Ji '546 or Ji '022 to arrive at the invention of claims 31, 32, and 34-35. Accordingly, Applicant requests that this rejection be withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicant believes the claims are in condition for allowance and requests early notification to that effect. If the Examiner believes there are any outstanding issues, she is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

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Version Showing Changes Made to Claims

1. (Thrice Amended) A vaso-occlusive composition consisting of a vaso-occlusive member selected from the group consisting of one or more vaso-occlusive coils, one or more filters, one or more retention devices and combinations thereof; and a bioactive material selected from the group consisting of fibrin; polyethylene glycol derivatives; thrombin-coated gelatin granules; balloons coated with iron microspheres; trace metals; thrombus-stabilizing molecules; at least one cytokine; extracellular matrix material; DNA; RNA; functional fragments of DNA, RNA, cytokines or extracellular matrix materials; and combinations thereof.

Claim 18 has been canceled without prejudice or disclaimer.

31. (Twice Amended) A vaso-occlusive composition comprising a vaso-occlusive coil, a liquid embolic material and an additional bioactive material selected from the group consisting of at least one cytokine; extracellular matrix material; DNA; RNA; functional fragments of DNA, RNA, cytokines or extracellular matrix material; and combinations thereof, wherein at least one of the bioactive materials is attached to the vaso-occlusive coil.

32. (Amended) The vaso-occlusive composition of claim 31, wherein the [particulate] liquid embolic material is a particulate material selected from the group consisting of microspheres, granules and beads.

34. (Twice Amended) The vaso-occlusive composition of claim 31, wherein the vaso-occlusive coil is [biodegradable] absorbable.

35. (Amended) The vaso-occlusive composition of claim [31] 32, wherein the particulate material is [biodegradable] absorbable.

Currently pending claims

1. (Thrice Amended) A vaso-occlusive composition consisting of a vaso-occlusive member selected from the group consisting of one or more vaso-occlusive coils, one or more filters, one or more retention devices and combinations thereof; and a bioactive material selected from the group consisting of fibrin; polyethylene glycol derivatives; thrombin-coated gelatin granules; balloons coated with iron microspheres; trace metals; thrombus-stabilizing molecules; at least one cytokine; extracellular matrix material; DNA; RNA; functional fragments of DNA, RNA, cytokines or extracellular matrix materials; and combinations thereof and wherein the vaso-occlusive member is selected from the group consisting of one or more vaso-occlusive coils, one or more filters, one or more retention devices and combinations thereof.

2. Canceled.

3. (Amended) The composition of claim 1, wherein the bioactive material is at least one cytokine.

4. The composition of claim 3, wherein the cytokine is selected from the group consisting of PDGF, β FGF, VEGF and TGF-beta.

5. The composition of claim 1, wherein the material comprises a trace metal.

6. The composition of claim 5, wherein the trace metal comprises copper.

7. The composition of claim 1, wherein the material comprises a thrombus-stabilizing molecule.

8. The composition of claim 7, wherein the thrombus-stabilizing molecule is Factor XIII or functional fragments thereof.

9. The composition of claim 7, wherein the thrombus-stabilizing molecule is plasminogen activator inhibitor-1 (PAI-1) or functional fragments thereof.

10. The composition of claim 7, wherein the thrombus-stabilizing molecule is α_2 -antiplasmin or functional fragments thereof.

11. (Amended) The composition of claim 1, wherein the bioactive material is adsorbed to the vaso-occlusive member.
12. Canceled.
13. Canceled.
14. The composition of claim 1, wherein the vaso-occlusive member is plasma treated.
15. The composition of claim 1, wherein the vaso-occlusive member is subjected to ion implantation.
16. The composition of claim 1, wherein the vaso-occlusive member is microtextured.
17. (Amended) The composition of claim 11, wherein the vaso-occlusive member includes a tie-layer between the vaso-occlusive member and the bioactive material.
18. Canceled.
19. A method of occluding a vessel comprising administering to a subject in need thereof a vaso-occlusive composition according to claim 1.
20. Canceled.
21. (Twice Amended) The method of claim 19, wherein the cytokine is selected from the group consisting of PDGF, EFGF, VEGF and TGF-beta.
22. The method of claim 19, wherein the trace metal is copper.
23. The method of claim 19, wherein the thrombus-stabilizing molecule is selected from the group consisting of Factor XIII, α_2 -antiplasmin, plasminogen activator inhibitor-1 (PAI-1), combinations thereof and functional fragments thereof.
24. The method of claim 19, wherein the vessel is an aneurysm.

25 to 30. Withdrawn.

31. (Twice Amended) A vaso-occlusive composition comprising a vaso-occlusive coil, a liquid embolic material and an additional bioactive material selected from the group consisting of at least one cytokine; extracellular matrix material; DNA; RNA; functional fragments of DNA, RNA, cytokines or extracellular matrix material; and combinations thereof, wherein at least one of the bioactive materials is attached to the vaso-occlusive coil.

32. (Amended) The vaso-occlusive composition of claim 31, wherein the liquid embolic material is a particulate material selected from the group consisting of microspheres, granules and beads.

33. Canceled.

34. (Twice Amended) The vaso-occlusive composition of claim 31, wherein the vaso-occlusive coil is absorbable.

35. (Amended) The vaso-occlusive composition of claim 32, wherein the particulate material is absorbable.

36. A method of occluding a vessel comprising administering to a subject in need thereof a vaso-occlusive composition according to claim 31.